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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,642	12/04/2001	Adam Kois	10624-049-999	6698

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EXAMINER	
FORD, JOHN M	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/004642	Kois et al
Examiner	**Group Art Unit**
J M Ford	1634

—The MAILING DATE of this communication appears on th cover sheet beneath th correspondence address—

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on Dec 18, 2003.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1, 2, 7--14, 24-27 and 38 is/are pending in the application.

Of the above claim(s) 14 and 25-27 is/are withdrawn from consideration.

☒ Claim(s) 1, 2, 7-11, 13, 24 and 38 is/are allowed.

☒ Claim(s) 12 & 14 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Atta hment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Int rvi w Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Acti n Summary

Applicants' response is noted.

The claim sin the application is claims 1, 2, 7-14, 24-27 and 38.

Claims 1, 2, 7-11, 13, 24 and 38 are allowed.

Claim 12 is rejected under 35 USC 112 1st paragraph. An inflammatory condition responsive to IKK-2 inhibition does not comply with the Utility Guidelines.

The recent utility guidelines set by USPTO require the claim to meet the requirements as stated in Brenner v. Manson, 148 USPQ 689, which requires that Utility be developed to a point where "specific benefits exist in currently available form." Similar is the "immediate benefit to the public" standard that Nelson v. Bowler, 206 USPQ 880 refers to. The standard set forth in the concurring opinion of In re Hartop, 135 USPQ 419 is "whether the invention has been brought to such perfection as to be capable of practical employment." This language is echoed in Bindra vs. Kelly, 206 USPQ 570. Laboratory Screen Test are not acceptable assays do not establish utility.

A broad disclosure of utility as in the cited claims cannot be deemed in compliance with 35 U.S.C. 112, first paragraph.

The PTO has amended the guidelines to clarify "specific utility.". The court focused on the fact that the applicant failed to identify a "specific utility" in Brenner v. Manson. The utility need be one in the real World of Commerce.

Claim 14 is too diverse to indicate anyone specific disease. The diseases in claim 14 are too diverse, many of which do not have an established regimen of treatment. MPEP 806.05 (h) provides for restricting out such a claim where it alleger more than one use for the compounds, and would require considerable proof.

Claim 14 is rejected under 35 USC 112, 1st paragraph as it is not reasonable to conclude that any one compound could have all of those uses.

Claim 14 is not reasonable, and requires prosecution to limit the claims to one specific utility or a very few number of uses related to anti-inflammatory, is this case.

This requirement to a specific utility is consistent with International PCT Rule 13.2 in PCT application, and 37 CFR 1.475 in National application prosecuted under 37 CFR 371.

The agreement to examine one specific use of the compounds, once the compounds are found allowable, is based on their being "of the same scope".

Claims 25—27 are rejected as they are additional active ingredient claims, therefore, not of the same scope as claim 1.

The search is different, depending or what the additional active ingredient is, and would be too burdensome to under lack here.

Claims 25-27 are withdrawn, as they are not of the same scope as claim 1, due to additional active ingredients.

JOHN M. FORD
PRIMARY EXAMINER
Group Art Unit 1624